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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,376	12/31/2003	Keith A. Rindlesbach	01845-22396	4892

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EXAMINER	
CHOI, FRANK I	

ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
05/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/750,376	RINDLESBACH, KEITH A.	
	Examiner	Art Unit	
	FRANK I. CHOI	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claim 31 recites clavulanate potassium. Augmentin ®, the combination of amoxicillin and clavulanate potassium, is recited in the Specification, however, the same refers to the source, i.e. manufacturer, and not the product. As such, the Specification should be amended as appropriate to set forth the actual active agents, including clavulanate potassium, contained in Augmentin ®.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. There is insufficient evidence to establish that administration of amoxicillin, vitamin B12, indomethacin, S-adenosyl-L-methionine, selenium and at least one of ibuprofen and aspirin will be effective in reducing the effects of Alzheimer's Dementia.

The nature of the invention:

The invention is directed to a method of reducing the effects of Alzheimers Dementia by administering amoxicillin, vitamin B12, indomethacin, S-adenosyl-L-methionine, selenium and at least one of ibuprofen and aspirin.

The state of the prior art and the predictability or lack thereof in the art:

The prior art does not appear to disclose or suggest said combination for the treatment of Alzchimer's Dementia. Treatment appears to be limited to providing appropriate levels of stimuli and haloperidol to deal with any anxiety (See Merck Manual (16th Ed. 1992), pp. 1406, 1407. Further, as indicated below, patients with severe dementia have been known to become lucid apparently independently of any drug intervention. As such, predictability appears to be low.

The amount of direction or guidance present and the presence or absence of working examples:

Although the specification provides information as to doses, working examples are not sufficient to establish that the claimed process is effective in reducing the effects of Alzheimer's Dementia. The working example appears to consist of only a single patient without any controls. See Declaration of Keith A. Rindlesbach (3/26/2007). However, it is known that patient's with severe dementia, including Alzheimer's patients, can have episodes of lucidity. See Normann et al. (2002), entire document, especially the abstract, Normann et al. (1998), entire document, especially the abstract. The examples set forth in the Specification do not rule out lucid episodes that are not related to drug therapy and do not indicate the duration of the treatment and extent and type of improvement of the dementia. The Examiner has considered the inventor's Declaration (3/26/2007), however, the declaration's conclusory statement as to the effect of the

treatments set forth in Examples 1 and 2 of the Specification is not supported by any data or records.

The breadth of the claims and the quantity of experimentation needed:

The claims are broad in that they claim a method of reducing the effects of Alzheimer's Dementia administering amoxicillin, vitamin B12, indomethacin, S-adenosyl-L-methionine, selenium and at least one of ibuprofen and aspirin in any amount, dosing interval and/or arrangement of the steps. As such, in light of the above, one of ordinary skill in the art would be required to do undue experimentation in order to determine at what dosing intervals, order of dosing, etc. which would be effective in reducing the effects of Alzheimer's dementia in a given patient and to establish that the reduction of the effects of Alzheimer's dementia was due to the dosing regimen as opposed to spontaneous lucidity unrelated to the drug treatment.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive.

The Applicant argues that the one of ordinary skill in the art could follow the examples exactly, however, the claims are not limited to the examples. Further, the examples fail to provide sufficient evidence that the treatment was effective in reducing the effects of Alzheimer's dementia.

As indicated above, the declaration does not provide sufficient evidence to show that the method as claimed is effective in reducing the effects of Alzheimer's Dementia in a patient. The Applicant provides no evidence that the experimentation is the type typically engaged by those skilled in the art or skilled in the art most closely associated with the invention. See *In re Knowlton*, 183 USPQ 33,37 (C.C.P.A. 1974)(where the record consisted substantially of

arguments and opinions of applicant's attorney, the court indicated that factual affidavits could have provided important evidence on the issue of enablement). Since patients with dementia can become lucid, the testing of a single patient is insufficient to establish that the claimed methods would be effective reducing the effects of Alzheimer's Dementia. The claimed method does merely require determining doses, dosing intervals, order of dosing, etc., the claimed method also requires that the same be effective in reducing the effects of Alzheimer's Dementia. As such, the Normann et al. references are clearly relevant to the enablement issue herein as the Applicant's experiments in a single patient do not show that the particular dosing regimen in the examples them selves much less over the entire scope of the claims was effective in reducing the effects of Alzheimer's Dementia as opposed to spontaneous lucidity not related to the treatment. The claims are still broad in that there is no limitation as to dosage, dosage interval and/or arrangement of the steps. Since there is insufficient support in the Specification to establish that the claimed method is what resulted in said reduction, undue experimentation would be required in order to determine what dosage, dosage interval and/or arrangement of the steps would be effective in reducing the effects of Alzheimer's dementia and to determine that the same was not the result of spontaneous lucidity.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Wednesday and Thursday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
May 13, 2009

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616